



Written Testimony of

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The Next Flu Pandemic: Evaluating U.S. Readiness

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Mr. Chairman and members of the Committee, thank you for the opportunity to provide our views on *The Next Flu Pandemic: Evaluating U.S. Readiness*. As a non-profit, non-partisan organization dedicated to saving lives by protecting the health of every community and working to make disease prevention a national priority, Trust for America's Health (TFAH) maintains that proactive, coordinated public health actions can help mitigate the impact of a pandemic influenza outbreak.

TFAH has just released a report, "*The Killer Flu?*," that provides a state-by-state examination of potential deaths and hospitalizations due to a flu pandemic based on model estimates; a state-by-state examination of capacity to treat citizens with recommended antivirals based on model estimates; a review of United States and state pandemic readiness, including a comparison to other nations' progress; and recommendations for improved pandemic readiness. I would like to submit the report in its entirety for the hearing record.

Overall, the report finds that despite the health and economic implications of such an event, pandemic planning efforts are lagging in the U.S., especially when compared to the United Kingdom (U.K.) and Canada.

The report also points out that the U.S. has not assessed or planned for the disruption a flu pandemic could cause both to the economy and society as a whole. This includes daily life considerations, such as potential school and workplace closures, potential travel and mass transit restrictions, and the potential need to close businesses resulting in complications in the delivery of food and basic supplies to people. Daily life and economic problems would likely emerge in the U.S. even before the pandemic flu hit the country due to the global interdependence of the world economy.

An equally troubling finding establishes that aspects of the planning process, such as ensuring vaccine and antiviral capabilities and surge capacity readiness, are incomplete or fragmented.

Mr. Chairman, TFAH maintains that the failure to establish a cohesive, rapid, and transparent U.S. pandemic strategy could prove a major weakness against a virulent and efficient virus -- putting Americans needlessly at risk.

That is why we believe that Congress and the Administration must take steps now to ensure that the nation's public health system and the health care delivery system will be able to respond to a major health crisis -- even beyond some of our fears of bioterrorism or chemical terrorism. While experts predict a pandemic flu may be "inevitable," subsequent death rates predicted to be in the millions are not. What will make the difference? We need strong, directed and rapid federal leadership, we must convert national and state pandemic influenza plans into operational blueprints, and we should increase vaccine production and capacity, procure adequate vaccines and antivirals for treatment, and stockpile additional medical supplies and equipment.

Pandemic Readiness: Moving from Planning to Action

Mr. Chairman, simply put, U.S. pandemic influenza preparedness is inadequate. Both the federal pandemic plan and various state pandemic plans are insufficient blueprints for an effective national response to a pandemic influenza.

Although a positive first step, the federal pandemic flu plan issued last August by the Department of Health and Human Services (DHHS) is still a draft. Moreover, the draft plan lacks specificity in several key areas, which were enumerated in comments received by the Department during the public comment period. TFAH believes that a final pandemic influenza plan must become a priority for this Administration and should provide the operational blueprint for the six pandemic phases as defined by the World Health Organization (WHO).

At the state level, most public health agencies have developed draft pandemic response plans, but they are in widely different phases of readiness. Many states have asked for additional and more specific guidance from the DHHS. Some are refusing to make their plans public even though many experts believe that public availability of plans is essential to improve integration with other jurisdictions, health care providers, and first responders.

TFAH believes that the Centers for Disease Control and Prevention (CDC) should formally review and approve state pandemic influenza plans in order to ensure nationwide preparedness standards and to facilitate regional coordination. Further, we urge CDC to require states to make approved plans publicly available. Perhaps most importantly, TFAH believes that pandemic flu preparedness activities at the federal, state and local levels should be supported with specific funding and not come at the expense of other preparedness efforts.

At the beginning of a pandemic, there may be an insufficient supply of vaccines and antivirals. A key element of pandemic planning is to determine protocols for allocation of vaccines and medicines among high priority populations, such as health care workers and public safety workers, prior to an outbreak.

As we learned last winter, prioritization is also important for the annual flu, when vaccine is in short supply. With the recent announcement by Chiron that its manufacturing capacity for this year's influenza vaccine will fall short, it would be prudent for CDC and DHHS officials to provide specific guidance now to states' health agencies as to which sectors of the population should receive antiviral medications and vaccines. In addition, CDC should immediately put into place measures that would assure equal geographic access to vaccines so that the nation does not face a shortage of annual influenza vaccine, with some states having excess supply and others unable to meet the demand for high-risk groups. This would help prevent the widespread confusion, long lines of worried elderly Americans, and the vaccine distribution issues that plagued last year's flu season.

With respect to federal leadership, TFAH urges the President to designate a senior official, whose primary responsibility is to assure Cabinet-level coordination of the federal government's response to a pandemic and also to ensure coordination between civil society (non-governmental economic infrastructure) and government during a pandemic.

Ultimately, there should be a government-wide pandemic preparedness plan, not just one that centers on health-related matters and DHHS activities.

Further, we believe that the CDC, in consultation with other federal agencies, should develop and implement a public education campaign about pandemic influenza and preparedness, including information on the potential need for general vaccination and personal precautionary measures. The agency should also develop a plan for communicating with the business community to provide information about the potential economic consequences of a pandemic, including the possibility of mass absenteeism and the potential need to convert certain facilities (e.g. hotels) as surge capacity treatment centers.

Stockpiling Vaccines, Medicines, Medical Supplies and Equipment

Building a stockpile for a pandemic is a responsible public health measure and TFAH maintains that adequate preparedness includes stockpiling *both* a vaccine and antivirals. However, we remain deeply concerned that the stockpiles will not be built fast enough and will not be large enough.

The U.S. is very late in entering the market for significant bulk purchase of Tamiflu, an antiviral that can treat symptoms of influenza and reduce the severity of the infection. With current production capacity, it could be sometime in 2007 before the stockpile ordered today is available. Most Tamiflu is produced abroad and requires nearly one year to manufacture. We believe that the Department should take immediate steps to work with industry to increase domestic production capacity, to assure that the stockpile is built quickly, and to assure that in the event of a pandemic Tamiflu will continue to be available to Americans.

It is also not clear that the amount of Tamiflu ordered is sufficient to address the demand in a pandemic. Other countries are following WHO estimates of a pandemic affecting at least 25 percent of the population, and have ordered enough Tamiflu to treat all who might be sick. This would translate to over 70 million courses in the United States. Some, such as the Infectious Diseases Society of America, have called for stockpiling as much as 124 million courses of Tamiflu for treatment and prevention of avian flu.

TFAH remains even more concerned about vaccine production capacity. In a pandemic, we can target antiviral treatment to those who are already sick, but must provide vaccines to all who are at risk -- which in this case would be all Americans. It is not at all clear that U.S. domestic vaccine producers could rapidly manufacture hundreds of millions of doses of a pandemic flu vaccine.

Most experts estimate there will be a lag time of six to nine months before a vaccine can be produced in sufficient quantities to protect individuals against a pandemic strain of influenza to which most people will have no natural immunity. While issues around vaccine manufacturing, distribution, safety and access are complex, other nations are putting protocols in place now with respect to creating a rapid response approval process for a pandemic flu vaccine. For example, regulators in the U.K. are already working with vaccine manufacturers to develop a model application for approval of a pandemic vaccine.

TFAH believes that the Food and Drug Administration (FDA) should immediately begin work with potential manufacturers of a pandemic flu vaccine to develop in advance the specific criteria for rapid response approval of a pandemic vaccine, which might save a month or two in the time it takes from identifying the flu strain and having the capacity to vaccinate Americans.

We are also concerned about whether the U.S. has sufficient domestic production capacity for a pandemic flu vaccine. While a projected initial stockpile of 40 million doses is a start, we would need to be able to vaccinate the entire U.S. population against a pandemic strain. Only about half of the U.S. annual flu vaccine supply is generated within the U.S.; in a pandemic, products manufactured elsewhere may not be available to us. We believe DHHS should investigate the value of creating a reserve production capacity to assure rapid ramp up of production, something the Canadian government has contracted for in the event of a pandemic. This would be especially important in the event the pandemic strain is not avian flu, which means the current H5N1 stockpile would not be effective.

Therefore, we hope the Administration will work with Congress to find sufficient funding in Fiscal Year (FY) 2006 to increase stockpiles to true preparedness levels and create incentives for industry to increase U.S.-based Tamiflu and vaccine production.

Vaccines and antivirals are not the only supplies that need to be stockpiled in preparation for a pandemic. Federal officials should also address the need to stockpile medical supplies that will be necessary to combat a pandemic. Currently, most health providers order and stock supplies on a “just-in-time” basis. This means they often have only a few days of reserve supplies, equipment, and medicines, including many basic protective items, such as masks, gloves, gowns, and clean hospital linens, many of which are produced in Asia, which may be the epicenter of a pandemic. That’s why we believe steps must be taken immediately to stockpile additional supplies, particularly since during an outbreak, many production and delivery systems for supplies will likely be stalled or even stopped.

Additional Recommendations

“*A Killer Flu?*” details a series of specific recommendations that would bolster U.S. readiness to combat an influenza pandemic. In addition to the recommendations related to operationalizing pandemic plans, government-wide coordination and leadership, vaccine production and the need to stockpile vaccines, antivirals and medical supplies, TFAH believes that Congress, the Administration and state health officials should take the following actions:

- **Define Roles and Responsibilities**

A clearly-defined organizational structure and chain of command is essential for rapid and efficient control and response, both in the federal government and at the state and local levels. Immediate planning should be occurring at the federal level to minimize disruption of the health care system and the overall economy. States must define and agree upon leadership roles and responsibilities with respect to who is in charge of a state’s public health and health care decisions. Plans must also designate liaisons to work with other jurisdictions and federal officials.

- **Outbreak Tracking**

Plans should ensure adequate laboratory surveillance of influenza, including the ability to isolate and subtype influenza viruses year round. Following federal guidelines outlined by DHHS, states should report all necessary data and information to federal and other health officials as soon as it becomes available. Congress should provide additional support for CDC's global surveillance activities, and the U.S. should support the WHO's surveillance program to assure as early a warning as possible for U.S. preparedness purposes.

- **Vaccine Research, Development, and Production**

The U.S. should continue to support and expand research into new technologies for influenza vaccine and clinical trials for potential avian flu and other pandemic vaccines. While the U.S. has issued limited contracts for stockpiling a potential pandemic vaccine, the federal government should also explore the Canadian approach of contracting for a reserve production capacity located in the U.S. A vaccine stockpiling approach is successful if public health authorities have guessed correctly on what the pandemic strain will be. A reserve production capacity can assure quick turnaround for production of a vaccine for the actual pandemic strain.

- **Mass Vaccination and Treatment Systems**

The federal government, in coordination with the states, must develop systems for tracking and distributing antiviral medication and vaccines. A national system is needed to assure targeted and/or equitable distribution of supply, so we do not have a repeat of the 2004-2005 flu season distribution problems. State-level systems also are needed to assure similar availability across a state. One of the best ways to improve vaccination preparations for a pandemic outbreak may be to enhance annual flu vaccination coverage for non-traditional high-risk groups (e.g. individuals with chronic diseases or compromised immune systems) to facilitate access to these populations.

- **Public Information Campaigns and Materials**

Communicating with the public in a clear and efficient manner is essential during a high-anxiety time. The federal government, in conjunction with the states, should develop coordinated messages for various audiences (media, public, providers, etc.) for each stage of a potential pandemic. States must identify and train spokespersons in multiple languages and educate public health officials, politicians, community leaders, partners, and the media about what information will and will not be available during a pandemic. States should ensure clear and consistent messaging by creating information templates in multiple languages ready for customization and distribution during a pandemic.

- **Surge Capacity Capabilities**

Plans must account for the likelihood that hospitals will be quickly overwhelmed during a pandemic, by developing auxiliary sites such as shelters, schools, nursing homes, hotels, and daycare centers for surge capacity treatment and for treatment of the “walking well.” States should be conducting surveys of potential sites and obtaining agreements.

- **Secure a Backup Workforce**

States should conduct and maintain an inventory of healthcare professional residents, including current and retired doctors, nurses, veterinarians, emergency medical staff, and other potential volunteers. These workers could be an essential expanded workforce during a pandemic. Pandemic survivors are also a population of potential workers. States should plan for tracking and soliciting volunteer support from this population, which is presumably immune to the virus.

- **Ensure Availability of Food, Water, and Other Supplies**

States must account for high demand for food, water, and other basic supplies, and plan for distribution to general and hard-to-reach populations. Plans should factor in potential complications that include: infected food and delivery workers, possible infected store facilities, and limitations on public interaction both for those infected and the general population at risk of exposure. Planners must also weigh the issue of “just-in-time” manufacturing of food and supplies, since reserves of supplies will not be available. Additionally, planners must address the limitations of medical equipment manufacturing, much of which Asia exports to the world.

- **Quarantine Measures and Authority to Close Public Places**

States must establish clear legal authority and emergency measures to effectively contain the spread of disease. States must have powers to prohibit public gatherings, close public facilities and schools, and restrict travel, if necessary.

- **Measures to Manage Mass Death**

Planning for worst-case scenarios is a critical component of effective planning. States must conduct and maintain an inventory of facilities with sufficient refrigerated storage to serve as temporary morgues in the event of a pandemic.

Such policies and investments will help stabilize the nation’s health and economy in the event of a pandemic while ensuring that pandemic readiness preparations are “commensurate with the scale of the threat we face.”

I thank you again for this opportunity to express TFAH’s views on evaluating U.S. readiness for the next flu pandemic.